K020045

BIOMET

CORPORATE HEADQUARTERS

JAN 3 0 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.
56 East Bell Drive
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
Telephone: (219) 267-6639

Proprietary Name: 3-piece Proximal Humeral Replacement System

Common Name: Shoulder prosthesis

Classification: Prosthesis, shoulder, non-constrained, metal/polymer cemented (21 CFR 888.3650)

Device Classification: Class II

Legally Marketed Device to which Substantially Equivalence is Claimed: The 3-piece Proximal Humeral Replacement System has been developed by modifying the Proximal Humeral Replacement System (K925613).

Device Description: The 3-piece Proximal Humeral Replacement System is a total shoulder prosthesis humeral component in cases where there has been severe proximal bone loss due to a tumor, trauma, or previous device placement.

The modified proximal humeral replacement device can be a combination of a proximal body and stem or proximal body, segment, and stem. The device is designed so that the distal portion of the stem is cemented into the remaining humeral bone with the stem collar, segment, and proximal body residing above the natural bone.

Indications for Use: The indications for use for the 3-Piece Proximal Humeral Replacement System include noninflamatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, treatment of acute fractures with humeral head involvement which are unmanageable using other treatment methods and oncology applications.

The 3-Piece Proximal Humeral Replacement System is for use with bone cement.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

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56 E. Bell Drive
Warsaw, IN 46582

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219.267.6639

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219.267.8137

E-MAIL
biomet@biomet.com

Summary of Technologies: The 3-piece Proximal Humeral Replacement System components-the materials, design, sizing, and indications are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical Testing with Engineering Justifications determined that the 3-piece Proximal Humeral Replacement System components presented no new risks and were, therefore, substantially equivalent to the predicate device.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet Orthopedics, Inc
P.O. Box 587
Warsaw, Indiana 46581

Re: K020045
Trade/Device Name: 3-Piece Proximal Humeral Replacement System
Regulation Number: 21 CFR 888.3650
Regulation Name: Prosthesis, shoulder, non-constrained, metal/polymer cemented
Regulatory Class: II
Product Code: KWT
Dated: December 19, 2001
Received: January 7, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K020045

DEVICE NAME: 3-Piece Proximal Humeral Replacement System

INDICATIONS FOR USE:

The indications for use for the 3-Piece Proximal Humeral Replacement System include noninflamatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, treatment of acute fractures with humeral head involvement which are unmanageable using other treatment methods and oncology applications.

This device is for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020045

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